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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,529	01/27/2004	Takayuki Inoue	248223US0	9555

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EXAMINER	
SOLOLA, TAOFIQ A	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,529	INOUE ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *08 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-5,7,8 and 17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,4,8,19,20 and 24* is/are rejected.

7)☐ Claim(s) *2-3, 5, 7, 17-18, 21-23, 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-5, 7-8, 17-25 are pending in this application.

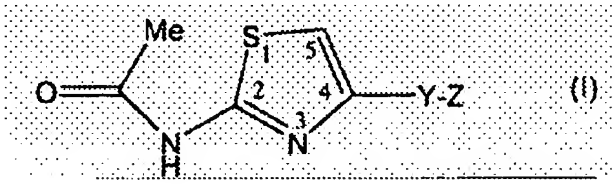
Claims 6 9-16 are cancelled.

RESTRICTION REQUIREMENT

In accordance with the last Office action and the amendment filed 12/8/05, additional species of the inventive compound have been searched. The restriction of non-elected inventions is now withdrawn.

Status of Claims

The Office has reviewed the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention encompasses all compounds within the scope of the claims, which fall into the same class and subclass as the elected compound, but may include additional compounds, which fall in related subclasses. Examination of the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification results in the following: In formula (I) below, Y is lower alkylene, lower alkenylene or –CONH, Z is as defined in claim 1.



As a result of the election and the corresponding scope of the invention identified herein, the remaining subject matter of claims 1-5, 7-8, 17-25 are withdrawn from further consideration by the Examiner, under 37 CFR § 1.142(b), as being drawn to a non-elected

subject matter. The withdrawn compounds are patentably distinct from the examined invention as they differ in structure and element and would require a separate search. They belong in different classifications. In addition, a reference, which anticipates the examined invention, would not render obvious the non-examined subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-20, 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19, 24 are drawn to treating any disease associated with VAP-1 or arising from its inhibition. Such is not a practical utility under the US patent practice except one reads the specification into the claims, which is contrary to the Office practice and precedent court decisions. Even then, reading the specification into the claims would make them duplicates of claim 20.

There is no support in the specification for using the instant compounds to treat all known diseases associated with VAP-1 or arising from its inhibition. This is an attempt by applicant to claim any disease that may be discovered in the future associated with VAP-1 or arising from its inhibition. Such is deemed a reach-through claim and is no longer patentable under the US patent practice. By deleting the claims the rejection would be overcome.

Claim 20 lacks adequate support in the specification. The claimed utilities are not supported in the specification by conclusive evidence or biological assays. The specification recites several utilities in page 11, line 14 to page 12, line 31. This and similar recitations are mere speculations. There is no known drug that is one-size-fits all.

Claims 19-20, 24 are rejected under 35 U.S.C. 112, first paragraph, because while the specification may be enabling for treating edema in diabetic patients, does not reasonably provide enablement for all the diseases listed in claim 20 or all the diseases associated with VAP-1 or arising from its inhibition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims.

"'In the context of determining whether sufficient "utility as a drug, medicant, and the like in human therapy" has been alleged, It is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the [utilities] as obviously correct." *In re Jolles*, 628 F.2d 1327, 1332 (Fed. Cir. 1980), citing *In re Novak*, 306 F.2d 924 (CCPA 1962); see Application of Irons, 340 F.2d 974, 977-78 (CCPA 1965). "A specification disclosure which contains a teaching of the manner and process of making and using the invention . . . must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), Id. at 1566, quoting *Marzocchi*, 439 F.2d 220, 223 (CCPA 1971); *Fiers v. Revel,* 984 F.2d 1164, 1171-72 (Fed. Cir. 1993), quoting *Marzocchi*, 439 F.2d at 223; see also Application of *Armbruster*, 512 F.2d 676, 677 (CCPA 1975); Application of *Knowlton*, 500 F.2d 566, 571 (CCPA 1974); Application of *Bowen*, 492 F.2d 859 (CCPA 1974); Application of *Hawkins*, 486

F.2d 569, 576 (CCPA 1973). Where there is "no indication that one skilled in the art would accept without question [the instant methods of using] and no evidence has been presented to demonstrate that the claimed products do have those effects *Novak*, 306 F.2d at 928, an applicant has failed to sufficiently demonstrate sufficient utility and therefore cannot establish enablement.'" *In re Rasmusson,* 75 USPQ2d 1297 (CAFC 2005). The claimed utility is not believable on its face for the following reasons.

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered. *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988):

1) Breadth of claims.

2) Nature of invention.

3) State of prior art.

4) Level of ordinary skill in the art.

5) Level predictability in the art.

6) Amount of direction and guidance provided by the inventor.

7) Existence of working examples.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breath of the claimed invention involves treating all the diseases listed in claim 20 or all the diseases associated with VAP-1 or arising from its inhibition. The nature of the invention is in the field of medicine wherein applicant claims a method of treating all the various conditions listed in claim 20 or all the diseases associated with VAP-1 or arising from its inhibition using compound of formula I.

The state of the prior art is what prior art knows about the nature of the invention. There is no known prior art that teaches a method of treating all the disease listed in claim 20 or all the

diseases associated with VAP-1 or arising from its inhibition with the same compound. The level of ordinary skill in the art is high but limited to increased VAP–1 enzyme activity in diabetics I and II patients who developed retinopathy. For example, see Diabetologia, (1999), Vol. 42, pages 223-227, Diabetic Med. (1999), Vol. 16, pages 514-521.

The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by applicant. In the instant invention the predictability is very low and consequently, the need for higher levels of direction and guidance by applicant. However, the amount of direction and guidance provided by applicant is limited to assays on VAP-1 enzyme activities in human and rat plasma, as well as ocular permeability study in diabetic rats. There are a very large variety of sources for the listed disorders because different mechanisms are involved. It is well known in the art that the mechanism of a specific disorder would dictate the choice of treatment compound. There is no evidence in the specification that established correlation between the assays and all the diseases listed in claim 20 or all the diseases associated with VAP-1 or arising from its inhibition. *See Ex parte Mass*, 9 USPQ2d 1746, 1987.

Therefore, the quantity of experimentation required to use the compounds as claimed, based on applicant's limited disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of biological experiments to determine which of diseases are treatable with the compounds. By limiting the disease to diabetes the rejection would be overcome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 4, 8, 19, 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons set forth above under 35 USC 112, first paragraph, claims 19, 24 are indefinite.

Claim 4 is not clear and therefore indefinite. It is not clear to determine what applicant intends to claim by "bivalent residue of thiazole". The claim must recite specific residues being claimed.

Claim 8 as written is not drawn what applicant regards as the invention. The product of the reaction step (i) is not within the scope of the compounds of formula (I). By deleting the step the rejection would be overcome.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Katsura et al., WO 9630350.

Katsura et al., disclose the marked compounds on the attached abstract.

Objection

Claims 1-5, 7-8, 17-25 are objected to for containing non-elected subject matter, and claims 2-3, 5, 7, 17-18, 21-23, 25 for being dependent on rejected claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

February 7, 2006